GILEAD | Medical Information

Bixlenvo™ (bictegravir/lenacapavir) Use in Hepatic Impairment

This document is in response to your request for information regarding Bixlenvo™ (bictegravir/lenacapavir [BIC/LEN]) in patients with hepatic impairment.

Some data may be outside of the US FDA-approved Prescribing Information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA approved prescribing information.

The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/BIXLENVO/BIXLENVO_pi

Product Labeling[1]

Use in Specific Populations

Hepatic impairment

No dosage adjustment of BIC/LEN is recommended in patients with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment. BIC/LEN has not been studied in patients with severe hepatic impairment (Child-Pugh Class C).

Clinical Pharmacology

Pharmacokinetics

Patients with hepatic impairment

Clinically relevant changes in the pharmacokinetics of BIC and LEN were not observed in participants with moderate (Child-Pugh Class B) hepatic impairment.

Available Data on BIC/LEN Use in Hepatic Impairment

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and August 10, 2026, using search terms that included bictegravir, lenacapavir, hepatic impairment and other related search terms. No relevant citations were found.

References

1. Enclosed, Gilead Sciences Inc. BIXLENVO™(bictegravir and lenacapavir) tablets, for oral use. U.S. Prescribing Information. Foster City, CA.

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Bixlenvo US Prescribing Information available at:
www.gilead.com/-/media/files/pdfs/medicines/hiv/BIXLENVO/BIXLENVO_pi

Follow Up

For any additional questions, please contact Gilead Medical Information at:

☎1-866-MEDI-GSI (1-866-633-4474) or 🖱 www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🖱 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

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